

ATTACHMENT 1
PROPOSED OUTLINE OF SDS

LIST OF ABBREVIATIONS

1. SUMMARY
2. INTRODUCTION
 - 2.1 Overview of Product Acceptability Principles
 - 2.2 Acceptability
 - 2.3 Overview of IOM Regulatory Principles
 - 2.4 Principles of Harm Reduction
3. PRODUCT DESCRIPTIONS (CA/E-4/F/JLI-Bridging/JLI)
 - 3.1 EHCSS Cigarette versions
 - 3.2 Lighter/Heater versions
4. NON-CLINICAL STUDIES
 - 4.1 Smoke Chemistry
 - 4.2 Mutagenicity
 - 4.3 Cytotoxicity
 - 4.4 Rodent Inhalation Studies
 - 4.4.1 90-day Inhalation Studies
 - 4.4.2 21-day Deposition Studies
 - 4.4.3 35-day Inflammation Studies
 - 4.5 Environmental Tobacco Smoke Studies
 - 4.6 Summary of Non-clinical Studies
5. CLINICAL STUDIES
 - 5.1 Table of clinical studies (titles and study numbers)
 - 5.2 Summaries of clinical studies
 - a. Objectives
 - b. Background, rationale for study
 - c. Products tested
 - d. Site(s) for clinical and laboratory work
 - e. Investigator(s)
 - f. Time, when study and laboratory work was performed
 - g. Study design
 - h. Study population

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- i. Methods of investigation and standards of performance
 - i. Clinical
 - ii. Questionnaires
 - iii. Topography
 - iv. Environmental tobacco smoke
 - v. Laboratory
 - 1. Clinical
 - 2. Bioanalytical
 - 3. Microbiology (Ames)
- j. Data collection and analysis
- k. Results
 - i. Study population, demographics, drop outs
 - ii. Protocol deviation
 - iii. Clinical including adverse events
 - iv. Questionnaires
 - v. Topography
 - vi. Environmental tobacco smoke
 - vii. Laboratory
 - 1. Clinical
 - 2. Bioanalytical
 - 3. Microbiology (Ames)
- l. Conclusions

5.3 Clinical summary

- a. Biomarkers, selection rationale
 - i. Exposure and biologically effective dose
 - ii. Potential harm
- b. Summary table of all clinical studies with
 - i. Study number
 - ii. Design
 - iii. Products tested
 - iv. Number of subjects
 - v. Biomarkers
 - vi. Statistical methods
 - vii. Comments
- c. Summary tables and figures of all clinical studies with
 - i. Biomarker results
 - ii. Adverse events
 - iii. Statistical results

6. Conclusions from clinical exposure testing